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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,869	01/24/2002	Hiroshi Nagasawa	NAGASAWA=7	5352
1444	7590	03/12/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/053,869

Applicant(s)

NAGASAWA, HIROSHI

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 22 September 2003 in which claims 1-4 were canceled; claim 5 was amended; claims 6-10 were added; and the Abstract was amended and further in view of supplemental papers filed 23 December 2003 in which claims 6-10 were amended and claim was canceled.

All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 21 April 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection necessitated by amendment are discussed.

Claims 6-10 are under prosecution.

### ***Specification***

2. The abstract, as amended 22 September 2003 is approved.

### ***Claim Objections***

3. Claim 8 is objected to because of the following informalities: Claim 8 incorrectly recites "üm" for "µm".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “a substrate of non-porous material” is added to the newly amended independent claim 6 from which claims 7-10 depend. However, the specification fails to define or provide any disclosure to support such claim recitation. The specification, in the paragraph spanning pages 8-9, teaches the substrate as follows:

“The substrate may be a material unchanged and stable to the detection system, and needs to have surface characteristics suitable for fixing of the carrier. The preferred substrate is a glass substrate such as quartz glass or boro-silicate glass, or an inorganic substrate such as a silicon wafer. However, an organic substrate such as a polyester film or a polyethylene film can be used, if a method for bonding it to the carrier can be worked out. Suitable surface treatment can be applied to the surface of the substrate in order to adjust, for example, compatibility with a carrier binder.”

The specification teaches examples of substrates i.e. glass, quartz glass, boro-silicate glass, silicon, polyester film and polyethylene film. However, the specification does not teach a generic “non-porous” substrate as claimed. Furthermore, the specification does not teach

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that any of the substrates have non-porous properties. Hence, the specification does not describe the newly claimed invention.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Beattie (U.S. Patent No. 5,843, 767, issued 1 December 1998).

Regarding Claim 6, Beattie discloses a reaction probe chip comprising a substrate (e.g. glass or silicon, Claim 11) in the "form" of a sheet (i.e. planar, Fig. 1A) and having a plurality of discrete through-holes; a carrier made of porous material in the through-holes (i.e. porous wafer, Fig. 1B); and probe molecules attached to a surface of the carrier wherein the probe

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molecules in a first group of through-holes are different from the probe molecules in a second group of through-holes (e.g. Example 11, Column 21, line 55-Column 22, line 18).

Furthermore, Beattie discloses the substrate as described in the instant specification i.e. silicon wafer (Example 3 & 11, Column 13, lines 24-49) or glass (Claim 11). Hence, Beattie discloses the probe chip as claimed.

Regarding Claim 10, Beattie discloses the reaction chip wherein the probe molecules are selected from DNAs, RNAs, fragments thereof, oligonucleotides, antigens, antibodies, epitopes, proteins and functional sites (Column 2, lines 21-30 and Column 8, lines 55-67).

### **Response to Arguments**

8. Applicant argues that Beattie only discloses porous substrate e.g. a nano-channel glass or microporous silicon substrate. Applicant further argues that because the substrate is porous, the probes are immobilized on sidewalls of the channels “perhaps” as summarized in Claim 1. Applicant concludes by stating that in contrast to Beattie, the instant invention requires a substrate of non-porous material i.e. glass, silicon or plastic and probes fixed on a carrier within the through-holes.

The arguments have been considered but are not found persuasive for several reasons. First, as discussed above, the recitation “non-porous” is deemed new matter. Second, the claims are not limited to a substrate comprising glass, silicon or plastic. Therefore, arguments regarding these specific substrates are not commensurate in scope with the claims. Third, contrary to Applicant’s assertion that the substrates of Beattie are only nano-channel glass or microporous silicon, Beattie specifically claims a substrate comprising glass or silicon (Claim 11); Beattie teaches a preferred embodiment wherein the substrate is silicon (Example 3, Column 13, lines 24-49 and Fig. 3). Finally, the claims are drawn to probe molecules fixed to “a surface” of the carrier. The claimed “surface” encompasses any surface of the carrier. Hence, even if, as Applicant asserts, the probes of Beattie are fixed within holes of the carrier,

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the probe chip of Beattie meets the limitations of the claim. Furthermore, it is noted that Beattie specifically teaches "surface" modification for probe attachment (Column 13, lines 44-49).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843, 767, issued 1 December 1998) in view of Düsterhöft et al (U.S. Patent No. 6,451,260 B1, filed 9 March 1999).

Regarding Claim 7, Beattie discloses a reaction probe chip comprising a substrate (e.g. glass or silicon, Claim 11) in the "form" of a sheet (i.e. planar, Fig. 1A) and having a plurality of discrete through-holes; a carrier made of porous material in the through-holes (i.e. porous wafer, Fig. 1B); and probe molecules attached to a surface of the carrier wherein the probe molecules in a first group of through-holes are different from the probe molecules in a second group of through-holes (e.g. Example 11, Column 21, line 55-Column 22, line 18). Beattie teaches the chip wherein the porous carrier is in the form of interconnected network (Column 12, lines 22-43) but they do not define the interconnected network as a membrane of nonwoven fabric. However, porous carriers consisting of a porous membrane and/or non-

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woven fabric were well known in the art as taught by Düsterhöft et al who teach a similar substrate.

Düsterhöft et al disclose a reaction probe chip comprising a substrate having a plurality of through-holes (apertures, Column 6, lines 11-19 and Column 8, lines 46-56) and a carrier in the through-holes having probe molecules fixed thereto such that the probe molecules are different according to the through-holes wherein the carrier is selected from porous membrane, non-woven fabric and porous glass (Column 3, lines 37-60; Column 5, lines 26-42 and Claim 21). Furthermore, they teach their carriers are adaptable to suitable size (Column 20, lines 61-65).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the carriers of Düsterhöft et al to the carriers of Beattie based on their well known use and further more based on their size- adaptability as taught by Düsterhöft et al (Column 20, lines 61-65). One of ordinary skill in the art would have been motivated to utilized the size adaptable carriers of Düsterhöft et al to thereby provide carriers useful in various sized through holes and therefore for the added benefit of adaptability and convenience.

Regarding Claim 8, Beattie teaches the carrier having a pore size of between 0.1 $\mu$ m and 0.5 $\mu$ m (Column 12, lines 44-59) and Düsterhöft et al wherein the pore size is between 0.1 $\mu$ m and 0.5 $\mu$ m (Column 3, lines 38-40; Column 11, lines 41-60)

Regarding Claim 9, Düsterhöft et al wherein the pore size is between 1 $\mu$ m and 1005 $\mu$ m (Column 3, lines 38-40; Column 11, lines 41-60)



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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Conclusion**

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
March 11, 2004